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107

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/143,379 08/28/98 KOGANTY

R 042881/0119

EXAMINER

HM12/0705

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ART UNIT

PAPER NUMBER

1627

DATE MAILED:

07/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/143,379

Applicant(s)

Gandhi et al

Examiner

T. Wessendorf

Group Art Unit

1627



☒ Responsive to communication(s) filed on 4/6/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-44 is/are pending in the application

Of the above, claim(s) 1-31, 39, and 41 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 32-38, 40, and 42-44 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Applicants' statement that corrections and submission of formal drawing will be delayed until allowable subject matter is indicated is noted. However, since said formal drawings have not been submitted, the objection to the drawings is maintained as set forth in the last Office action.

Applicants' statement regarding the election of Group II, claims 32-41 and species (peptide platforms and anti-bacterial compounds) without traverse is noted. Also noted is the statement of applicants that the claims to Group I, drawn to a method of making, would have to be rejoined and examined in this application, once the product claims are found allowable.

Claims 33, 38 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 33 recitation of the carbohydrates "reacted with a MUCI core protein to produce a library is inconsistent with the recitation in the base claim 32 of reacting a peptide scaffold with the carbohydrate to produce a library. The core (larger size) protein of claim 33 would broaden the recitation of a smaller size amino acid sequence, peptide. Also, it is suggested that applicants provide for the complete name of the abbreviated MUCI. This rejection also applies to claim 44.

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B). Regarding claim 38, the "like" phrase e.g., "antibody-like" is still present in the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 34-38, 40 and 42-43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rao et al (5,795,958) for reasons advanced in the last Office action (12/6/99), pages 5-6.

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Applicants admit that Rao discloses a collection or library of glycopeptide but argues that the method by which Rao made the glycopeptide library is different from the instantly claimed library. It is well settled that patentability of a product is based not on the process by which the product is made rather, whether the product has been established in the prior art. Applicants have not tended any comparative evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). Because of the nature of product by process claims, the examiner ordinarily cannot focus on the precise difference between the claimed product and the disclosed product, the burden is upon the applicants to come forward with evidence establishing any difference. Applicants' further arguments as to the difference in size and diversity of the instant library from the glycopeptide library of Rao is not commensurate in scope with the claims as the argued properties are limitations not appearing in the instant claims. It is further argued that the variations in the library of Rao is only drawn to the peptide residues. Contrary to applicants' arguments, Rao discloses at e.g., col. 21, lines 44-49 not only variations in the amino acid residues but also variations in the multiple carbohydrate residues of the peptide derivatives. The carbohydrate residues that can be varied include N-acetylgalactosamine, inter alia.

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Claims 32 and 34-38 are rejected under 35 U.S.C. 102(b) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vetter et al (WO 95/18971) for reasons set forth in the last Office action, page 6, last paragraph.

Applicants admit that Vetter (page 25) describes a combinatorial aspect with amino acid variations in the peptide sequence, except for the O-allyl protected aspartic acid, which remains constant as the sole glycosyl acceptor. Nevertheless, argue that the library carries a single carbohydrate structure with no provision for further iterative synthesis leading to one more complex structures, as in the randomly glycosylated libraries according to applicants' invention. Vetter discloses at e.g., page 26, lines 19-31 a first set of resin bound glycosylated library of glycoconjugates (introduced to the various aliquots of resin beads containing surface reactive functionality. The aliquots of the original 184 member library were diversified by conjugation to 17 different glycosylamines, inter alia, NGal). See further the response under Rao, supra regarding applicants' arguments as to the process by which the product is made.

The rejection over Schleyer is withdrawn in view of applicants' argument. However, it is noted that the instant specification does not contain a specific reference or claim to

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the prior provisional application(s) as the first sentence of the specification (37 CFR 1.78). [Amendment to the specification to reflect the claim to said provisional application should be made].

Claims 32-37 are rejected under 35 U.S.C. 102(b) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frische et al (abstract of J. Pept. Sci.)

Since applicants merely apply the same arguments above hence, the response under Rao and Vetter above is applied herein.

Applicants' further arguments as to the size and diversity produced by the combinatorial libraries as exemplified by MUC3 is noted. However, none of the claims recite for MUC3. Rather, the claims recite for MUC1.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Courtenay-Luck discloses the minimum recognition unit of a PEM mucin tandem repeat specific monoclonal antibody and detection method.

2. Alvarez discloses abtides binding to epithtelial mucin.

Claims 33 and 44 are free of prior art.

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This application contains claim 1-31, 39 and 41 drawn to an invention nonelected without traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


T. Wessendorf
Patent Examiner
Art Unit 1627
7/3/00